Remarks

Claims 1-17 are pending. Claim 5 has been amended to correct the dependency. Structures 1, 23, 37, 59, 73, 139, 154, 217, 229, 266, 281, 293, 302, and 330 in Table I have been amended to correct typographical errors which occurred when Table I was reconstructed in the amendment and response filed on November 28, 2005. Support for the amendment is found, for example, in Table I in the application as originally filed. Structure 71 has been canceled as it is a duplicate of structure 1. Claim 10 has been amended to delete the phrase "or expression of SR BI".

Applicants believe that it is proper for the present amendment to be entered since it places the application in condition for allowance. Alternatively, entry of this amendment is proper since it places the claims in better form for appeal, does not raise any new issues, and does not require further consideration or search. Additionally, by amending claims, the claimed subject matter is narrowed since it is limited to a method of identifying a compound which alters SR-BI binding activity or expression comprising screening a library of small molecule compounds using a high throughput screening assay determining alteration of HDL binding by SR-BI or SR-BI-mediated lipid transport.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent it applies to the claims as amended.

The Examiner alleges that the phrase "Table 1" in claim 1 renders claim 1 and it's dependent claims indefinite because it is not clear if claim 1 is a compound claim, a composition claim, or a method claim. The Examiner's objection is unclear. Claims 1-3

are clearly directed to a pharmaceutical composition. Claims 4-17 are clearly directed to a method of screening. Claims 1-17 are definite.

The Examiner alleges that claim 1 is indefinite because it refers to a table of compounds which are not in the claims but in the disclosure. By the Examiner's own admission, incorporation by reference to a specific figure or table is permitted in exceptional circumstances "when there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim". *Ex Parte Fressola*, 27 U.S.P.Q.2d 1608, 1609 (Bd. Pat. Appl. & Inter. 1993).

Table 1 contains over 300 compounds. It is clearly more concise for claim 1 to incorporate table 1 by reference than to reproduce all 300 compounds in claim 1. The compounds contained in claim 1 have very different structures and therefore cannot be described by a genus. Therefore, claim 1 is definite. In order to facilitate prosecution, however, the applicants are willing to amend claim 1 to include the structures of the compounds in claim 1 if the Examiner so wishes. The same arguments apply to claim 4.

The Examiner alleges that claim 2 is a duplicate of claim 1 as there is no material difference between claim 1 and claim 2. Claim 1 is directed to a pharmaceutical composition comprising a compound selected from the group shown in Table 1, which specifically alters the binding activity of SR-BI, in combination with a pharmaceutically acceptable carrier. Claim 2 is directed to the composition of claim 1 in a dosage formulation comprising an amount effective to treat a human or animal in need thereof. Claim 2 recites an effective amount of the composition of claim 1. An effective amount of the compound is dependent on the formulation, active ingredient, and the condition

and class of patients to be treated, among other variables. Claims 1 and 2 are of a different scope.

The Examiner alleges that claim 5 is an improper dependent claim as it depends on claim 4, which is a method claim, and claim 1, which is a composition claim. Claim 5 has been amended to delete the reference to claim 1.

Rejection Under 35 U.S.C. § 102

Claims 1-3 were rejected under 35 U.S.C. § 102(b) as being anticipated by the Chembridge Diver Set brochure ("brochure"). Claims 10-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0099040 to Krieger *et al.* ("Krieger") and U.S. Patent No. 5,965,790 to Acton ("Acton"). Applicants respectfully traverse this rejection.

Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 USPQ 81 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 USPQ2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, Id.:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 USPQ 649, 653 (Fed. Cir. 1986).

Analysis

Claim 1 is directed to a pharmaceutical composition comprising a compound selected from the group shown in Table 1, which specifically alters the binding activity of SR-BI, in combination with a pharmaceutically acceptable carrier.

Chembridge Driver Set Brochure

The Examiner alleges that the Chembridge Driver Set brochure identifies the compounds as drugs and thus anticipates claim 1. Such an allegation is incorrect. The Chembridge Driver Set does not identify the compounds as drugs. It describes them as

drug-like small molecules. The brochure does not disclose or suggest a pharmaceutical composition comprising a compound of Table 1, which specifically alters the binding activity of SR-BI, in combination with a pharmaceutical carrier.

Finally, the Chembridge Driver Set contains between 10,000 and 50,000 compounds. There is no teaching or suggestion in the borchure that the 300 or so compounds in Table 1 specifically alter the binding activity of SR-BI. The United States Court of Customs and Patent Appeals, in *In re* Schauman, held that the disclosure of a chemical genus in a reference constitutes a description of a claimed specific compound falling within the genus where the reference stated preferences for the genus point to specific compounds and the genus embraces a very limited number of compounds closely related to one another in structure (*In re* Schaumann, 572 F.2d 312, 316, 197 U.S.P.Q. 5 (CCPA 1978)). The compounds disclosed in the brochure are not a limited set (the number of compounds ranges from 10,000 to 50,000) which are closely related to one another in structure.

In order to anticipate a claim, the reference must disclose each and every element of the claims. The brochure does not disclose each and every element of the claims. Therefore, claims 1-3 are novel over the Chembridge Driver Set brochure.

Krieger

Krieger was published on July 25, 2002. The applicants' priority date is October 8, 2002. Therefore, Krieger is not available as prior art under 35 U.S.C. § 102(b). At most, Krieger is only available as prior art under 35 U.S.C. § 102(a) or § 102(e). It is the Examiner's position that claims 10-17 are not entitled to the priority date of the provisional application because the provisional application does not include all the

compounds of Table 1. A review of Table 1, on pages 33-45 of the provisional application, shows that these compounds are identical to the compounds shown in Table 1 in the utility application. Structures 1, 23, 37, 59, 71, 73, 139, 154, 217, 229, 266, 281, 293, 302, and 330 in Table 1 have been amended to correct typographical errors that occurred when Table 1 was reconstructed in the amendment and response filed on November 28, 2005. The Examiner has not indicated which, if any, of the compounds in Table 1 in the present application are not shown in Table 1 in the provisional application. Further, even if the Examiner's allegation was correct, claims 10-17 do not refer to the compounds in Table 1. Therefore, claims 10-17 are entitled to the priority date of the provisional application. As such, Krieger is only available as prior art under 35 U.S.C. § 102 (a) or (e).

Krieger does not disclose or suggest either a high throughput assay for screening a **library of small molecule compounds** as defined by amended claims 10-17. Therefore, claims 10-17 are novel over Krieger.

Acton

The Examiner alleges that applicants argue that Acton is not available under 35 U.S.C. § 102(b). Such an allegation is incorrect. The applicants argued, in the Amendment and Response filed November 28, 2005, that U.S. Patent Application Publication No. 2002/0016364 to Luchoomun was not prior art under 35 U.S.C. § 102(b).

It is the Examiner's position that claims 10-17 are not entitled to the priority date of the provisional application because the provisional application does not include all the compounds of Table 1. A review of Table 1, on pages 33-45 of the provisional application, shows that these compounds are identical to the compounds shown in Table

1 in the utility application. Structures 1, 23, 37, 59, 71, 73, 139, 154, 217, 229, 266, 281, 293, 302, and 330 in Table 1 have been amended to correct typographical errors that occurred when Table 1 was reconstructed in the amendment and response filed on November 28, 2005. The Examiner has not indicated which, if any, of the compounds in Table 1 in the present application are not shown in Table 1 in the provisional application. Further, even if the Examiner's allegation was correct, claims 10-17 do not refer to the compounds in Table 1. Therefore, claims 10-17 are entitled to the priority date of the provisional application.

Acton describes **nucleic acid molecules** that encode human SR-B1 receptor transcription as well as an assay for screening nucleic acid molecules, which encode SR BI, and, generally, assays to identify molecules that modulate (agonize or antagonize) transcription from an SR-B1 transcriptional nucleic acid, thereby activating, increasing, or suppressing the expression level of a gene under the control of the transcriptional nucleic acid (*see* col. 26). Acton does not disclose or suggest a method of identifying a compound which alters SR-B1 activity or expression comprising screening a library of small molecule compounds using a high throughput screening assay by **determining alteration of HDL binding**. Claim 10 has been amended to delete assays for inhibition or expression of SR BI.

Allowance of claims 1-17, as amended, is respectfully solicited.

Respectfully submitted,

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Date: June 8, 2006

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